Savi
TECHNOLOGY

November 22, 2004

Dr. Paul Rudolf, M.D, J.D.
Divison of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, MD 20850

Reference Number: Radiofrequency Identification Feasiblity Studies and Pilot Progams for Drugs

Dear Dr. Rudolf:

Savi Technology, Inc. is pleased to submit our comments to the Food and Drug Adminisration's Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs. We are an industry leader in Radio Frequency Identification (RFID)-based supply chain visibility, security, and management and an ISO 9001 compliant RFID manufacturer, software developer, and Automated Identification Technology (AIT) solutions provider. Savi is the

- Hardware provider for the existing 1000+ node DoD RFID network,

- Prime Contractor for the DoD's RFID II contract, and has

- Demonstrated the business process analysis, engineering and go live support for military shipping solutions from CONUS to combatant commands for supplies and unit equipment.

After reviewing the proposed "Guidance for FDA Staff and Industry Compliance Policy Guides, Sec. 400.210, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs dated November 2004", Savi Technology would like to submit for consideration, the potential inclusion of active RFID transponder and reader products operating at the 433.92MHz (UHF), and 123KHz (LF) ranges.

Savi Technology is the industry leader in the development and manufacturing of active RFID technology. Since 1989, Savi Technology has provided active RFID products, software, services and support for both commercial and government clients. Most noteworthy is the fact that Savi Technology is currently the sole source active RFID vendor to the DOD, and has continued as the incumbent active RFID vendor to the DOD since 1994. Since 1997, Savi Technology has provided over 1,100,000 active RFID transponders to the DOD, in addition to over 1,000 active RFID readers, located in 50 countries, which comprises the largest active RFID network in the world. This active 433.92MHz network was developed by the DOD specifically to track and electronically manifest ISO shipping containers, air pallets, and unit equipment. Since 2001, Savi Technology has expanded its product series to include active RFID electronic security seal and environmental sensor products to meet the container security demands of Department of Homeland Security (DHS) sponsored evaluations including: Operation Safe Commerce, phase I and phase II. Additionally, the DOD demands for environmental sensor RFID products for commodities including medical supplies, as well as meals and ammunition, have spurred Savi Technology to develop a range of integrated

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environmental sensor enabled 433.92MHz active RFID transponders, which are safe for use around both sensitive medical supplies and un-shunted munitions.

Based on our extensive experience in providing active RFID products for in transit tracking, electronic manifesting, security and environmental monitoring to the DOD and DHS, Savi Technology can conclusively demonstrate that our EchoPoint product series' dual frequency bandwidth (433MHz for send and receive, in addition to the optional use of 123KHz for receive only commands related to portal locating) have proven to be both extremely reliable in metal-rich environments; and compliant with frequency approval requirements throughout most of the world. Additionally, Savi Technology's air protocol is fully compliant with FCC Part 15, and ISO 18000 Part 7 requirements, which ensures that our active RFID products are industry standard, non-proprietary, and operate in an open architectures. Because our EchoPoint products feature active, battery operated transponders to power the UHF reader response to commands, reader EIRP is a fraction of similar passive reader devices.

We feel the inclusion of the 433MHz and 123KHz frequency bandwidths will greatly enhance the outcome of potential RFID studies and pilots throughout the pharmaceutical industry. Savi Technology welcomes the opportunity to provide a more detailed briefing on our active RFID products at your earliest convenience.

Please feel free to contact Erin Scales, escales@savi.com on 301.217.0147 with any questions. We look forward to working with you in the future.

Sincerely,

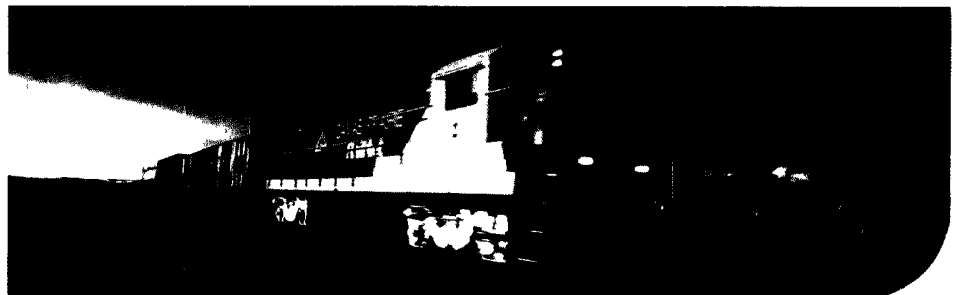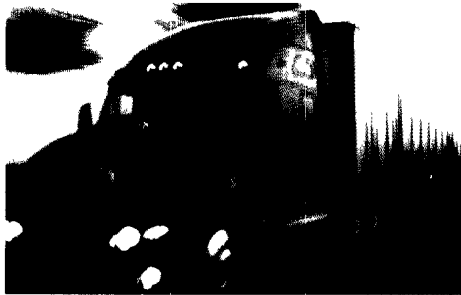David Stephens
Senior Vice President, Public Sector

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Erin K. Scales
Senior Account Executive
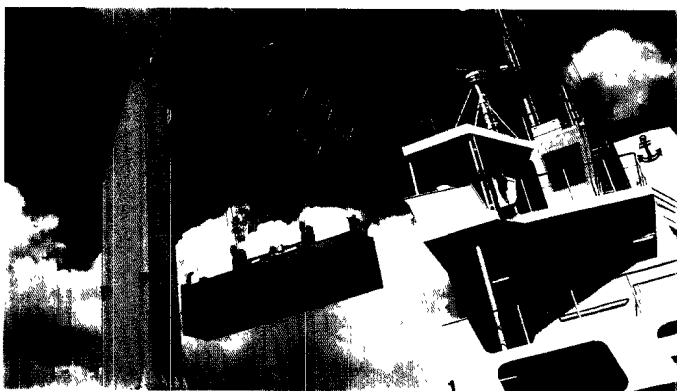
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Reliability • Flexibility • Scalability • Service

With over 15 years of logistics infrastructure experience, Savi Technology is the proven leader in building Radio Frequency Identification Technology (RFID) and Automatic Identification and Data Collection (AIDC) networks that deliver real-time global supply chain visibility, asset management, inventory optimization, and shipment security.

Optimize your business value with Savi's complete supply chain RFID networks — tags, readers, middleware, software applications, and services.

Savi

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RFID Visibility
For Supply Networks

With over 15 years of logistics infrastructure experience, Savi Technology is the proven leader in building Radio Frequency Identification Technology (RFID) and Automatic Identification and Data Collection (AIDC) networks that deliver real-time global supply chain visibility, asset management, inventory optimization, and shipment security.

Savi provides supply chain asset management, security and inventory optimization software that is uniquely integrated with Automatic Identification and Data Collection (AIDC) systems to create scalable networks that deliver a new generation of real-time logistics solutions.

Savi Across Industries

Savi's industry solutions provide the infrastructure, platform, network operating system and applications to address specific industry challenges. Many industries benefit from Savi's real-time solutions. trucks, rail-cars, conveyances, suppliers for retail and defense, medical, transportation, ports, terminal operations, exporters, importers and third party logistics providers to name a few Some of the key industries benefiting from Savi's real-time solutions include:

Defense Logistics. Savi's Defense Logistics Solution addresses the various challenges facing military logistics within a global supply chain Lack of visibility as shipments leave the warehouse to the field, combined with the manual processes at storage depots, results in lost and delayed shipments of mission-critical supplies and ammunition. With an RFID network infrastructure and consignment tracking system, shipments are tracked in real-time, providing complete supply chain visibility from factory to foxhole.

Defense Suppliers. Suppliers to the U.S. DoD face new challenges with recent RFID policies. **Savi's Defense Supplier Solution** enables defense suppliers to adhere to the new requirements, while at the same time receiving a positive return on their RFID investment with Savi's proven global RFID solution and extensive experience working with the U.S. DoD

Asset Owners. Savi's Asset Optimization Solution addresses inefficient manual container cycles, excessive amounts of asset safety stock, and the waste of valuable time and resources spent looking for "lost" assets. By sending automatic notification messages about impending shipments, and enabling the transport of goods to retail outlets on a just-in-time basis, inventory levels are kept accurate and up to date to minimize safety stock and reduce labor costs, while optimizing asset utilization.

Global Importers/Exporters. Savi's solution for global importers and exporters fulfills in-stock, fill-rate and production objectives while consistently controlling costs involved with incorrect material allocation, missed shipment times and lost shipments. With **Savi's Compliance, Visibility and Security Solution,** shippers have comprehensive, real-time information from source-to-destination about asset status including location, condition of contents (humidity, temperature, shock, etc.), security of the shipment, and deviations from shipping routes and schedules.

Transportation. Air, Rail, Truck, Ocean — Cargo theft, loss, and damage have long been serious problems for the transportation world With the constant threat of terrorists using the freight transportation system as a vehicle for weapons of mass destruction, transportation companies struggle to implement cost-effective security measures without slowing down the flow of shipments. **Savi's Transportation Solution** combines event and process management software with real-time asset tracking and monitoring through the integration of automatic identification and data collection technologies such as RFID, electronic seals, biometrics, sensors, and satellite tracking systems. Savi's Transportation Solution provides automated alerts that instantly notify security, operational managers, and appropriate law enforcement agencies the moment there is a breach in security and supply chain protocol
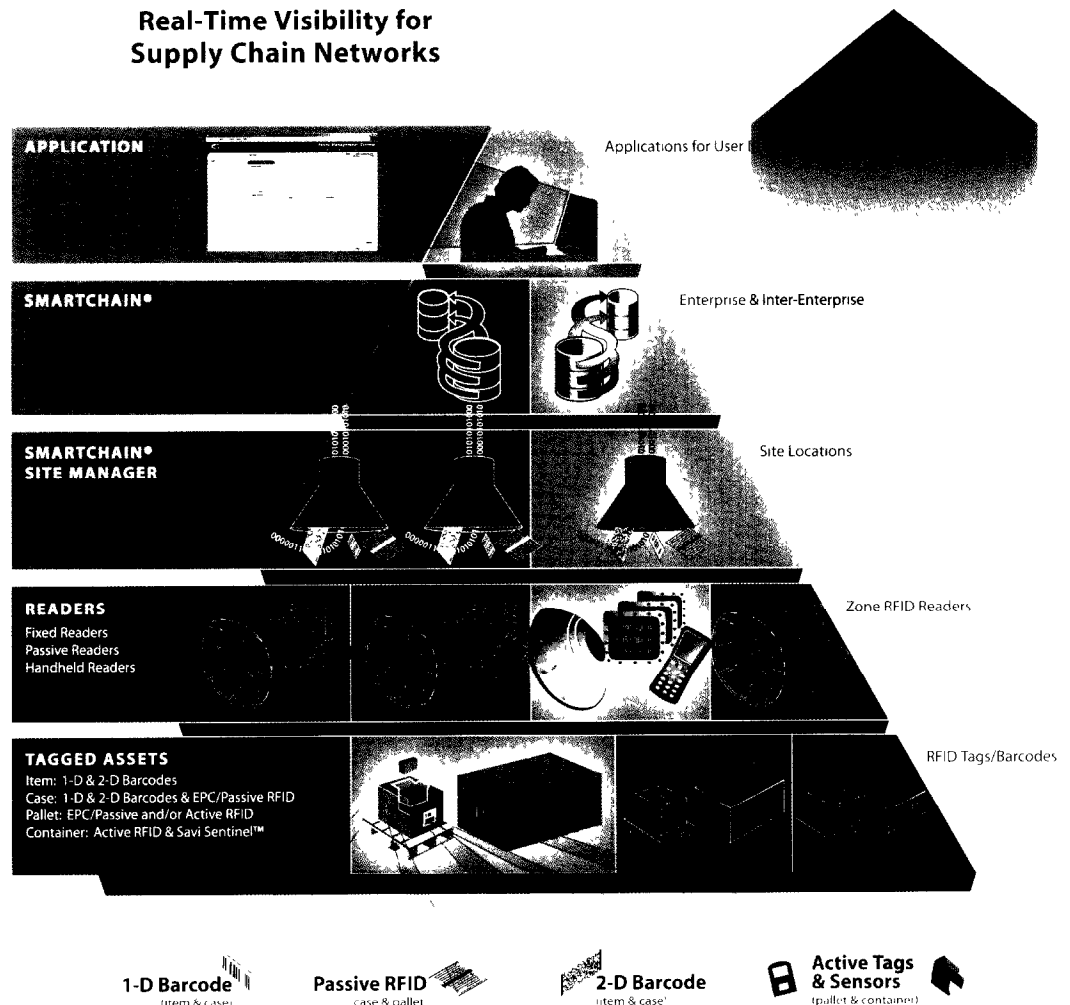
Savi Products—Providing Supply Network Visibility

The integration of RFID and Automatic Identification and Data Collection (AIDC) technologies with their core information systems will create more reliable, more efficient, and more predictable supply networks. Today, companies must respond to the AIDC opportunity and make decisions on moving forward that will have long lasting implications for operational efficiency and market competitiveness.

Many of these decisions will have to be made with the best available information, knowing that certain conditions and requirements will constantly change Operating in such uncertainty makes future proofing a critical aspect of almost any vendor or technology selection. Savi understands the importance of investing in future-proofed products and solutions that create successful RFID networks.

An RFID network connects and communicates across various nodes and sites along a supply chain. The network may span several nodes and sites, or may be part of a much larger global supply chain. Savi has proven experience with successful RFID network implementations around the world and can enable your business to become a part of your own RFID network.

Real-Time Visibility for Supply Chain Networks

Savi's products and solutions are architected on three key attributes that enable a future-proof RFID network infrastructure.

- **Modular:** Savi's RFID networks are based on a modular architecture that lets you take a building block approach so you can grow your infrastructure as you grow and extend your business.

- **Open:** Savi's networks are built to industry standards, and are designed to integrate any form of AIDC technology and adapt to the unique conditions of any given environment.

- **Scalable:** Savi's innovative federated network architecture is uniquely capable of scaling from a single company solution to a vertical industry or tradelane to a global network

With this complete solution, ports, terminals, asset owners, shippers and logistics service providers gain complete visibility into their logistics processes and are able to make better, more dynamic decisions about their supply chain assets and the contents they carry.

Savi EchoPoint™—Tags, Readers, Signposts

Savi's unique data collection capabilities include Savi's own active, data-rich RFID tags, readers and signposts seamlessly integrated with other forms of Automatic Identification and Data Collection (AIDC) technologies such as bar codes, passive RFID, sensors, electronic seals, and satellite systems. At the data collection layer, Savi's products, working with other AIDC technologies, are the building blocks for your integrated RFID network.

SaviTags, Savi Readers and Savi Signposts are all built on Savi's innovative EchoPoint technology:

- **SaviTag ST-654** — Savi's high performance active data-rich RFID tag for tracking assets and their contents

- **SaviTag ST-604** — Savi's active RFID tag for tracking metal assets

- **SaviTag ST-602** — Savi's active RFID tag designed for general asset tracking

- **Savi Sentinel** — Savi's active RFID tag with multiple sensors for securing and monitoring integrity and condition of ISO containers and their contents

- **Savi SR-650 Fixed Reader** — Savi's fixed interrogator that collects location and status data from RFID tags within a 100m range

- **Savi Mobile Reader** — A mobile, low profile, lightweight, battery operated interrogator/reader

- **Savi Signposts** — Savi Signposts communicate with tags within their immediate vicinity, enabling precise identification of tagged assets and their locations

SmartChain® Supply Network Operating System

Savi SmartChain is a real-time supply network operating system that provides the most scalable and comprehensive platform available for AIDC/RFID networks. SmartChain incorporates the functionality of a middleware platform, operating system, data repository, event engine, and advanced components that translate and process all supply chain data into valuable business information. SmartChain can acquire and manage data from virtually any source, including bar code scans, active and EPC passive RFID tag readers, GPS, traditional EDI, and application-generated data. SmartChain makes sense of all of this data by translating it into a common language, then filtering, aggregating, and processing it into actionable information.

SmartChain Site Manager is a fundamental building block of the Savi SmartChain solution, providing an integrated, node-level management system for data collection and system configuration. By consolidating device and data management for a specific installation or location, SmartChain Site Manager simplifies operations and lowers total cost of ownership, while simultaneously providing a stand alone functionality that can be seamlessly incorporated into a network of nodes as a modular component. The benefits of SmartChain Site Manager range from streamlined management of disparate AIDC devices to assured "future-proofed" investment protection as AIDC technologies advance.

Savi SmartChain Applications

Savi SmartChain Applications extend **Savi's SmartChain Platform**. The final element in a complete supply chain solution, these full-featured applications enable asset visibility and management, as well as transportation security for enterprise companies.
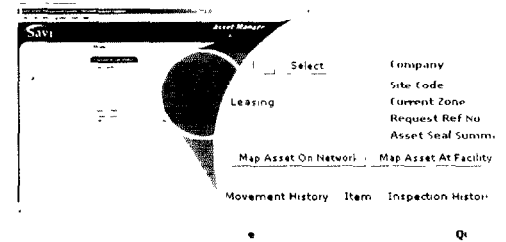
The **Savi Asset Management System (AMS)** enables companies to track asset location and status, search for and find those assets, and analyze historical information to identify and eliminate bottlenecks, understand asset utilization, perform instant inventories, manage asset losses, and more. Savi AMS leverages the value of complete, real-time information provided by SmartChain to maximize return on assets. By improving lifecycle management, recovering lost assets and enhancing operational efficiency, companies can reduce costs by increasing utilization of existing assets and subsequently reducing stock or on-hand inventory.

Savi   RFID Visibility for Supply Networks

The **Savi Transportation Security System (TSS)** is rule-driven event and process management software combined with real-time asset tracking and monitoring that utilizes a variety of automatic identification technologies such as RFID, electronic seals, biometrics, sensors and satellite tracking systems, and automated alerts that instantly notify security, operational managers, and appropriate law enforcement agencies the moment there is a breach in security protocol

Savi TSS allows companies to mitigate risks by increasing monitoring and visibility of goods flowing through the supply chain, and is designed for completeness by incorporating information from RFID and e-seals, as well as sensor data to produce state and exception reporting that is essential to ensuring that containers and cargo have not been tampered with
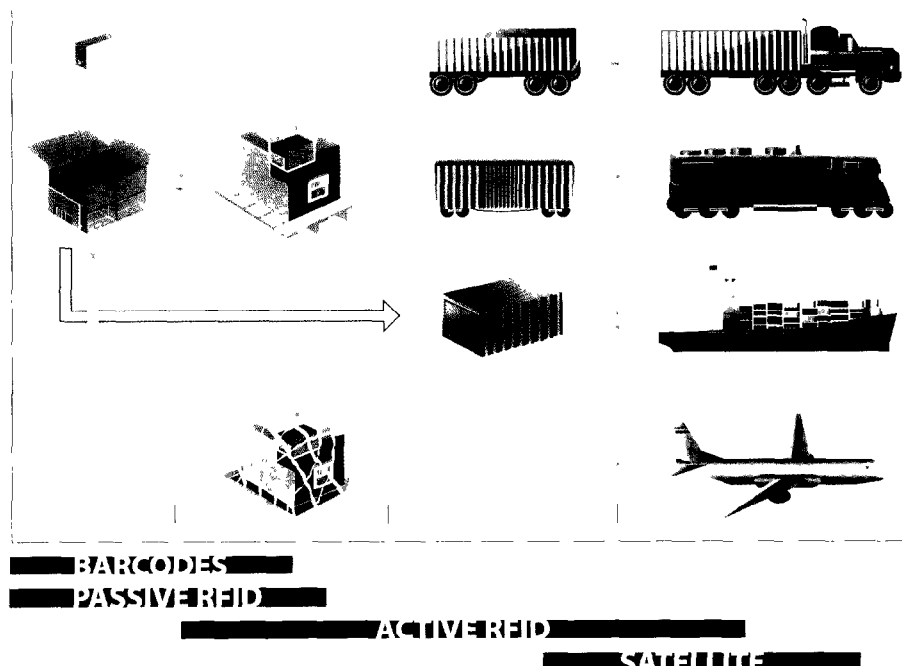
The **Savi Consignment Tracking System (CTS)** enables military logisticians to identify precisely where critical supplies are in the supply chain and when consignments will arrive at the frontline, thus ensuring that the right kit is in the right place at the right time Savi CTS provides real-time visibility of consignments giving logisticians control over the flow of materiel, giving the front-line unit visibility of where its demand is and when it will arrive, and giving the commander accurate information on when his forces will have the necessary equipment to conduct operations. Visibility of the supply pipeline has been proven to reduce both the instances of duplicate demands and depot stocks as the system moves from a just-in-case to a just-in-time methodology The web-based and real-time functionality provided by Savi CTS is designed to optimize any military supply system.

Savi and RFID Compliance—Extending Your Investment in RFID

Recent industry mandates by military defense departments and retail giants have forced supplier companies to comply with specific technical requirements. Savi understands the RFID infrastructure requirements these suppliers face and offers distinctive solutions to help meet these new demands. By leveraging Savi's extensive experience implementing complete global RFID supply chain networks, companies can realize a positive return on their investment in RFID by creating a more efficient supply chain while simultaneously optimizing operations as they work to meet specific industry RFID requirements.

Nested Visibility: End-To-End and Top-to-Bottom Item Level Visibility

Savi takes its RFID expertise to the next level by integrating our active RFID technology with other AIDC technologies. This unique integration results in "nested visibility" throughout the supply chain By providing visibility down to the items within a carton, companies gain a higher level of visibility to improve operations, reduce inventory, and minimize damaged and lost shipments.

BARCODES
PASSIVE RFID
ACTIVE RFID
SATELLITE

RFID Visibility for Supply Networks

Item level visibility and global security enable companies to:

- Consistently monitor the security and integrity of containers and their contents
- Significantly reduce the likelihood of a tamper event happening in-transit with container accountability from point of origin to destination
- Determine the specific contents missing from a container if a security breach does occur
- Reduce transit inventory cost and make more informed decisions on inventory forecasting
- Continue visibility and effective tracking of items after they have been removed from a conveyance

Savi in the Real World

Savi has more than a decade of experience implementing solutions around the world that have been proven to enhance operational efficiency and deliver substantial cost savings. We are the primary RFID technology provider for the world's largest wireless cargo monitoring network for the U S. Department of Defense, which employs RFID, barcode, cellular and satellite communications systems to track more than 35,000 conveyances daily across a global network of 1,400 locations in more than 45 countries. Since the late 1990s, through investments in research, development and technology acquisitions, the company has designed and developed a networked software platform, Savi SmartChain, for both the public and commercial sectors that is uniquely integrated with automatic data collection and identification systems to create RFID-based networks that deliver real-time supply chain management.

Beyond Savi's extensive work with global defense organizations, Savi also has a strong presence building and expanding RFID networks in the commercial world.

Savi's Global Consulting Services

Savi's Global Consulting Services teams are focused on achieving your business objectives from the first day of your project to the last—whether they are streamlining defense force supply chains, improving supply chain visibility to optimize inventory in global supply chains, optimizing asset utilization, improving operational efficiency or minimizing security threats.

Our unique methodology, processes and consulting tools, based on fifteen years of successful RFID and AIDC implementation experience, enables Savi's Global Consulting Services to deliver an RFID network implementation with lower costs, reduced risk, higher quality and minimized implementation time. This solid combination allows you to realize the maximum benefit from your RFID infrastructure investment in the shortest possible time.

Savi Partnerships—Extending the Global Network

Savi's security solutions have become an integral part of many international port infrastructures. Savi is a key partner and solution provider in the Smart & Secure Tradelanes (SST) initiative, a comprehensive security initiative for the ocean cargo community. SST incorporates best business practices, advanced technologies and supply chain security authorities in a global information network for container security. Other current SST partners include the world's largest port operators, major shippers, logistics services and solution providers.

With a solid fifteen-year history in RFID technology, Savi well understands that every company's supply chain practices are different and that requirements and objectives change within and between organizations and industries. On the foundation of this real-world experience, Savi has architected a unique supply network operating system that supports the full horizontal and vertical range of requirements for the real-time, integrated supply chain. Savi has the experience, know-how, and capabilities to address both near-term tactical supply chain challenges and long-term strategic opportunities.

Contact Savi

Founded in 1989, Savi Technology is privately held, with headquarters in Sunnyvale, California and offices in Johannesburg, London, Singapore, and Washington D.C. In the United States, call toll-free 800-428-0554, international customers dial 408-743-8000. Contact Savi Asia at 65.6241.1191 and Savi EMEA at + 44.1483.243617 (Great Britain), +2711 469-3144 (S. Africa) Visit www.savi.com or email us at sales@savi.com.

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